

Appl. No. 09/063,978  
Amdt. Dated November 15, 2005  
Reply to Office Action of September 19, 2005

Attorney Docket No. 81841.0041  
Customer No. 26021

REMARKS/ARGUMENTS:

Claims 1, 26, 33, and 34 are amended. Claims 1-42 are pending in the application. Reexamination and reconsideration of the application, as amended, are respectfully requested.

CLAIM REJECTIONS UNDER 35 U.S.C. § 112:

Claims 1-22, 26-30, 32-34, 37, 38, 41, and 42 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. The Examiner maintains the previous rejection stating that the claims drawn to a binding assay for sensing analyte mass are not enabled.

The Examiner further states,

"The claims fail to recite the necessary equilibrium conditions and ambient conditions to perform the method which determines analyte mass thereby failing to enabled the scope of the claims. Details for determining analyte mass are restricted to only using dose response curves."

The Applicant respectfully traverses this rejection. The Applicant respectfully submits that the claims and the specification recite conditions for determining analyte mass. For example, claim 1 recites in step b) "the analyte binding partner in the microscopic sorbent zone being present in excess relative to the analyte, so that any analyte present in the defined volume is substantially depleted from the sample and concentrated on the microscopic sorbent zone to form an analyte capture complex with the analyte binding partner." This condition is also recited in the Applicant's specification at page 3, lines 29-31. In addition, the Applicant's specification provides further guidance for optimizing the conditions: (1) utilizing sorbent materials having high affinity constants, e.g.,  $K_A > 10^{10}$  liter/mole,

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to give stronger binding; (2) minimizing the sample volume; and (3) utilizing a large initial mass of analyte binding partner as a capture reagent (page 14, lines 5-9). Furthermore, specific examples are given in the specification to demonstrate the conditions needed for determining analyte mass. For instance, at page 4, line 31- page 5, line 1, the specification provides: "The assay can be optimized using a defined volume of sample from about 50  $\mu$ l to about 500  $\mu$ l. Preferably, the amount of the analyte binding partner immobilized in a sorbent zone is from  $10^5$  to about  $10^{12}$  molecules of analyte binding partner and the diameter of the sorbent zones is about 60  $\mu$ m to about 500  $\mu$ m. Under these conditions, about  $10^5$  to about  $10^{10}$  molecules of analyte can be detected per sorbent zone." At page 10, lines 8-11, the specification provides: "The antibodies used will generally have conventional affinity constants on the order of about  $10^8$  to about  $10^{11}$  liters/mole, however high affinity antibodies, having affinity constants of about  $10^{12}$  to about  $10^{13}$  can also be used."

In view of the foregoing, the Applicant respectfully submits that the claims and specification are sufficiently enabling for a person of ordinary skill in the art to determine the analyte mass. However, in order to expedite the prosecution of the instant application, the Applicant amended independent claims 1, 26, 33, and 34 to include the limitation that the analyte mass is determined from a dose response curve. Therefore, claims 1, 26, 33, 34 and dependent claims 2-22, 27-30, 32, 37, 38, 41, and 42 positively recite that the analyte mass is determined from a dose response curve. Since the Examiner acknowledges that the claims are enabled by using dose response curves; and there are no further objections or rejections against claims 1-22, 26-30, 32-34, 37, 38, 41, and 42, allowance of these claims is thus respectfully requested.

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**ALLOWABLE SUBJECT MATTER:**

Claims 23-25, 31, 35, 36, 39, and 40 are allowable.

Applicant believes the foregoing amendments comply with requirements of form and thus may be admitted under 37 C.F.R. § 1.116(b). In addition, admission is requested under 37 C.F.R. § 1.116(b) as presenting rejected claims in better form for consideration on appeal.

In view of the foregoing, it is respectfully submitted that the application is in condition for allowance. Reexamination and reconsideration of the application, as amended, are requested.

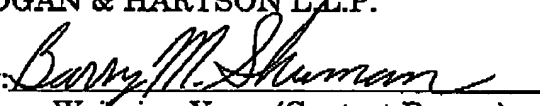
If for any reason the Examiner finds the application other than in condition for allowance, the Examiner is requested to call the undersigned attorney at the Los Angeles, California telephone number (213) 337-6700 to discuss the steps necessary for placing the application in condition for allowance.

If there are any fees due in connection with the filing of this response, please charge the fees to our Deposit Account No. 50-1314.

Respectfully submitted,  
HOGAN & HARTSON L.L.P.

Date: November 15, 2005

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